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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874,512	06/05/2001	David H. Sachs	59056.__	6693

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EXAMINER	
WEHBE, ANNE MARIE SABRINA	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 10/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/874,512	SACHS, DAVID H.	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's amendment received on 7/28/03 has been entered. New claims 24-36 have been added. Claims 19-36 are pending in the instant application. An action on the merits follows.

Those sections of Title 35, US code, not included in this action can be found in the previous office action.

Priority

The applicant acknowledges that the effective filing date for the pending claims is the filing date of the 08/458,720 application, which is June 1, 1995.

Claim Rejections - 35 USC § 102

The rejection of claims 19-20, and 23 and new claims 24-34 under 35 U.S.C. 102(b) as being anticipated by Chavin et al. (1994) Transplantation, Vol. 57, 736-740 is maintained. Applicant's amendments and arguments have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

The applicant's claims as amended recite a kit comprising an anti-CD2 antibody in a pharmaceutically acceptable carrier and an immunosuppressive agent, and instructions to administer a short course of the immunosuppressive agent at a high dose . The applicant further claims said kit wherein the anti-CD2 antibody is a monoclonal antibody and wherein the immunosuppressive agent is selected from a group consisting of cyclosporine, FK-506, and rapamycin. As noted in the previous office action, the applicant has stated that although the specification does not recite such kits *in haec verba*, the specification discloses combinations of pharmaceutical compositions and agents. Since the word "kit" has not been defined in the specification, the claims have been interpreted according to applicant's description of a combination of an anti-CD2 antibody and an immunosuppressive agent.

The applicant argues that the amendment of the claims to include instructions to administer a short course of the immunosuppressive agent at a high dose overcomes the teachings of Chavin et al. since Chavin does not teach using a short course of the immunosuppressive at a high dose. The applicant's argument is not persuasive. The applicant's claims are product claims, not method claims. As discussed in the previous office action, Chavin et al. teaches the combined administration of a monoclonal anti-CD2 antibody and an immunosuppressant such as cyclosporine, rapamycin or FK506 in order to increase graft survival in murine cardiac allograft recipients (Chavin et al., page 736, and page 737, Table 1). In particular, Chavin et al. teaches that anti-CD2 monoclonal antibody synergizes with FK506 to induce tolerance to allografts (Chavin et al., page 738, Table 2). Applicant's "instructions" represent an intended use of the

immunosuppressive agent and do not add any structural limitations to the kit as a whole or the immunosuppressive agents listed. Please note as well that the applicant's amendment is confusing since the claims are directed to a kit comprising two elements, an anti-CD2 antibody and an immunosuppressive agent, whereas the instructions are only directed to administration of the immunosuppressive agent. Thus, it is unclear whether the instructions provided even apply to the kit as a whole.

Furthermore, instructions as to the use of a product are not given patentable weight in a product claim where the body of the claim does not depend on the preamble or instructions for completeness but, instead, the structural limitations are able to stand alone. The MPEP states that,".. in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art." *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto* , 136 USPQ 458, 459 (CCPA 1963)(MPEP 2111.02). The office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 USPQ 1302, 1303 (BPAI 1993), *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ2d 1922, 1923 (BPAI 1989).

Thus, for the reasons of record discussed in detail above, the rejection of claims 19-20, and 23-34 stands.

Claim Rejections - 35 USC § 103

The rejection of claims 21 and 22, and new claims 35-36 under 35 U.S.C. 103(a) as being unpatentable over WO 94/20619 (9/15/94), hereafter referred to as Bazin et al., in view of Chavin et al. (1994) Transplantation, Vol. 57, 736-740, is maintained. Applicant's amendments and arguments have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

The applicant's claims as amended recite a kit comprising an anti-CD2 antibody in a pharmaceutically acceptable carrier and an immunosuppressive agent, wherein the anti-CD2 antibody comprises BTI-322 or an antibody which binds an epitope also recognized by BTI-322, and instructions to administer a short course of the immunosuppressive agent at a high dose.

The applicant argues that the added limitation that the kit includes instructions to administer a short course of the immunosuppressive agent at a high dose overcomes the rejection of record since Chavin et al. does not teach using a short course of the immunosuppressive agent at a high dose. The arguments directed to Chavin et al. have been addressed in detail above and have not been found persuasive due to the fact that the claims are product claims and that the instructions for use do not change or affect the structural properties of the products claimed.

Thus, for the reasons of record discussed in detail above, the rejection of claims 21-22 and 35-36 stands.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-36 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The applicant has amended to claims to recite "instructions to administer a short course of the immunosuppressive agent at a high dose". The claims as written are product claims directed to a kit comprising two elements, an anti-CD2 antibody and an immunosuppressive agent, whereas the instructions are only directed to administration of the immunosuppressive agent. It is unclear whether the instructions provided apply to the kit as a whole or are intended to apply only to the immunosuppressive agent separate from the recited combination. Furthermore, the term "high dose" is a relative term such that the metes and bounds of the claims cannot be determined.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 872-9306.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER